

What is Claimed is:

1. A method of upgrading a medical device comprising:
 - providing a medical device having a controller that controls operation of the medical device according to an operating routine executed by the controller, wherein a set of operating features of the medical device is determined based on the operating routine, and wherein an internal access key is associated with each set of operating features of the medical device;
 - providing an external device adapted to communicate with the controller;
 - establishing a communication link between the external device and the controller;
 - inputting an external access key to the external device;
 - comparing the internal access key provided by the medical device with the external access key; and
 - enabling upgrading of the medical device by enabling the operating routine to be modified responsive to the internal access key matching the external access key.
2. The method of claim 1, wherein the medical device is a pressure support system comprising a pressure generating system adapted to generate a flow of breathing gas, wherein the controller executes a first operating routine to control the operation of the pressure generating system according to a first set of operating features.

3. The method of claim 2, further comprising, after the enabling step, upgrading the medical device by providing a second operating routine from the external device to the controller, wherein the controller thereafter executes the second operating routine causing the pressure support system to operate according to a second set of operating features.

4. The method of claim 3, wherein the first set of operating features includes a first pressure support mode, and wherein the second set of operating features includes a second pressure support mode.

5. The method of claim 4, wherein the first pressure support mode is a bi-level pressure support mode, and wherein the second pressure support mode is a bi-level pressure support mode with a timed backup breath delivery capability.

6. The method of claim 1, wherein establishing the communication link includes providing a hard wired connection between the external device and the controller.

7. The method of claim 1, wherein inputting the external access key to the external device includes manually entering the external access key into the external device via a keypad associated with the external device, or reading the external access key from a memory associated with the external device.

8. The method of claim 1, further comprising downloading the external access key to the controller responsive to the internal access key being input to the external device, and wherein comparing the internal access key with the external access key takes place in the controller.

9. The method of claim 1, wherein each internal access key associated with each set of operating features of the medical device is (1) generated by the controller based on an access key generating algorithm each time the comparing step is to be performed, or (2) stored in advance in a memory in the medical device and recalled from the memory each time the comparing step is to be performed.

10. The method of claim 1, further comprising, after the enabling step, upgrading the medical device by providing an upgraded operating routine from the external device to the controller, wherein the controller thereafter executes the upgraded operating routine causing the medical device to operate according to an upgraded set of operating features.

11. The method of claim 10, wherein each internal access key associated with each set of operating features of the medical device is generated by the controller based on an access key generating algorithm each time the comparing step is to be performed, and further comprising storing the external access key in the medical device

as a new internal access key, and causing the controller to generate the new internal access key in a subsequent access key validation process.

12. A medical device upgrading system, comprising
a medical device including a controller that controls operation of the
medical device according to an operating routine executed by the controller and a
memory associated with the controller that stores the operating routine, wherein a set of
operating features of the medical device is determined based on the operating routine, and
wherein an internal access key is associated with each set of operating features of the
medical device; and

an external device adapted to communicate with the controller via a
communication link between the external device and the controller, wherein the external
device is adapted to receive an external access key, and wherein the controller or the
external device compares the internal access key of the medical device with the external
access key and enables upgrading of the medical device by enabling the operating routine
to be modified responsive to the internal access key matching the external access key.

13. The system of claim 12, wherein the medical device is a pressure
support system comprising a pressure generating system adapted to generate a flow of
breathing gas, wherein the controller executes a first operating routine to control the
operation of the pressure generating system according to a first set of operating features.

14. The system of claim 13, wherein the controller is adapted to receive a second operating routine from the external device responsive to the external access key matching the internal access key, and wherein the controller thereafter executes the second operating routine causing the pressure support system to operate according to a second set of operating features.

15. The system of claim 14, wherein the first set of operating features corresponds to a bi-level pressure support mode, and wherein the second set of operating features corresponds to a bi-level pressure support mode with a timed backup breath delivery capability.

16. The system of claim 12, wherein the communication link is a hard wired connection between the external device and the controller.

17. The system of claim 12, wherein the external device includes a keypad by which the external access key is manually entered into the external device.

18. The system of claim 12, wherein the external device is adapted to download the external access key to the controller, and wherein comparing the internal access key with the external access key takes place in the controller.

19. The system of claim 12, wherein the controller is adapted to generate each internal access key associated with each set of operating features of the medical device based on an access key generating algorithm executed by the controller each time an access key validation is required.

20. The system of claim 12, wherein the external device upgrades the medical device by providing an upgraded operating routine from the external device to the controller responsive to an upgrade being enabled, and wherein the controller thereafter executes the upgraded operating routine causing the medical device to operate according to an upgraded set of operating features.

21. The system of claim 20, wherein the controller generates each internal access key associated with each set of operating features of the medical device based on an access key generating algorithm each time an access key validation is required, stores the external access key in the medical device as a new internal access key, and generates the new internal access key in a subsequent access key validation process.

22. A medical device upgrading system comprising:
a medical device including:
processing means for controlling at least one operation of the medical device according to an operating routine executed by the processing means, and

memory means, associated with the processing means, for storing the operating routine, wherein a set of operating features of the medical device is determined based on the operating routine, and wherein an internal access key is associated with each set of operating features of the medical device; and

an external device adapted to communicate with the processing means via a communication link between the external device and the processing means, wherein the external device includes means for receiving an external access key, wherein the processing means or the external device includes means for comparing the internal access key of the medical device with the external access key and for enabling upgrading of the medical device by enabling the operating routine to be modified responsive to the internal access key matching the external access key.

23. The system of claim 22, wherein the medical device further includes a pressure generating system adapted to provide a flow of breathing gas to a patient under the control of the processing means, wherein the processing means executes a first operating routine stored in the memory to control the operation of the pressure generating system according to a first set of operating features.

24. The system of claim 23, wherein the processing means is adapted to receive a second operating routine from the external device responsive to the external access key matching the internal access key, and wherein the processing means thereafter

executes the second operating routine causing the pressure support system to operate according to a second set of operating features.

25. The system of claim 24, wherein the first set of operating features corresponds to a bi-level pressure support mode, and wherein the second set of operating features corresponds to a bi-level pressure support mode with a timed backup breath delivery capability.

26. The system of claim 22, wherein the communication link is a hard wired connection between the external device and the processing means.

27. The system of claim 22, wherein the external device includes a keypad by which the external access key is manually entered into the external device.

28. The system of claim 22, wherein the external device is adapted to download the external access key to the processing means, and wherein comparing the internal access key with the external access key takes place in the processing means.

29. The system of claim 22, wherein the processing means is adapted to generate each internal access key associated with each set of operating features of the medical based on an access key generating algorithm executed by the processing means each time an access key validation is required.

30. The system of claim 22, wherein the external device upgrades the medical device by providing an upgraded operating routine from the external device to the processing means responsive to an upgrade being enabled, wherein the processing means thereafter executes the upgraded operating routine causing the medical device to operate according to an upgraded set of operating features.

31. The system of claim 30, wherein the processing means generates each internal access key associated with each set of operating features of the medical device based on an access key generating algorithm each time an access key validation process is to be performed, stores the external access key in the medical device as a new internal access key, and generates the new internal access key in a subsequent access key validation process.

32. A method of processing and tracking an upgrade of a medical device, comprising:

identifying a medical device to be upgraded;
providing an upgrade request from an upgrade requester to a medical device supplier, wherein the upgrade request includes a first product identifier associated with the medical device to be upgraded and a requested upgrade of the medical device;

maintaining a database, available to the medical device supplier, that includes the first product identifier for the medical device and an external access key associated with both the medical device and an available upgrade;

accessing the database, by the medical device supplier, to determine an external access key associated with both the medical device to be upgraded and the requested upgrade;

providing the external access key to the medical device;

comparing the external access key with an internal access key associated with the medical device;

enabling an upgrade of the medical device responsive to the internal access key matching the external access key; and

updating the database to indicate that the medical device having the first product identifier has been upgraded with the desired upgrade.

33. The method of claim 32, wherein providing the external access key to the medical device includes providing the desired upgrade to the upgrade requester via a distribution media or a electronic communication link.

34. The method of claim 33, wherein providing the external access key and the desired upgrade includes providing the external access key on a first medium and providing the desired upgrade on a second medium.

35. The method of claim 32, wherein comparing the external access key with an internal access key takes place in the medical device to be upgraded.

36. The method of claim 32, wherein updating the database includes providing a second product identifier associated with the medical device.

37. The method of claim 32, wherein the medical device includes a controller that controls operation of the medical device according to an operating routine executed by the controller, wherein a set of operating features of the medical device is determined based on the operating routine, wherein the internal access key is associated with each set of operating features of the medical device; and

wherein providing the external access key to the medical device comprises:

providing an external device adapted to communicate with the controller,

establishing a communication link between the external device and the medical device, and

inputting an external access key to the external device.

38. The method of claim 37, further comprising, after the enabling step, upgrading the medical device by providing an upgraded operating routine from the external device to the controller, wherein the controller thereafter executes the upgraded

operating routine causing the medical device to operate according to an upgraded set of operating features.

39. The method of claim 38, further comprising providing the upgraded set of operating features to the external device from the medical device supplier.

40. The method of claim 38, wherein each internal access key associated with each set of operating features of the medical device is generated by the controller based on an access key generating algorithm each time the comparing step is to be performed, and further comprising storing the external access key in the medical device as a new internal access key, and causing the controller to generate the new internal access key in a subsequent access key validation process.

41. The method of claim 37, wherein the medical device is a pressure support system comprising a pressure generating system adapted to generate a flow of breathing gas, wherein the controller executes a first operating routine to control the operation of the pressure generating system according to a first set of operating features.

42. The method of claim 41, further comprising, after the enabling step, upgrading the medical device by providing a second operating routine from the external device to the controller, wherein the controller thereafter executes the second operating

routine causing the pressure support system to operate according to a second set of operating features.

43. The method of claim 42, wherein the first set of operating features includes a first pressure support mode, and wherein the second set of operating features includes a second pressure support mode.

44. The method of claim 43, wherein the first pressure support mode is a bi-level pressure support mode, and wherein the second pressure support mode is a bi-level pressure support mode with a timed backup breath delivery capability.

45. The method of claim 37, wherein establishing a communication link includes providing a hard wired connection between the external device and the controller.

46. The method of claim 37, wherein inputting an external access key to the external device includes manually entering the external access key into the external device via a keypad associated with the external device, or reading the external access key from a memory associated with the external device.

47. The method of claim 37, wherein comparing the internal access key with the external access key takes place in the controller.

48. The method of claim 37, wherein each internal access key associated with each set of operating features of the medical device is (1) generated by the controller based on an access key generating algorithm each time the comparing step is to be performed, or (2) stored in advance in the medical device and recalled from memory each time the comparing step is to be performed.

49. A method for a medical device supplier to process and track an upgrade of a medical device:

receiving, from an upgrade requester, an upgrade request including first product identifier associated with the medical device and a desired upgrade;

maintaining a database, available to the medical device supplier, that includes the first product identifier for the medical device and an external access key associated with both the medical device and an available upgrade;

accessing the database, by the medical device supplier, responsive to receiving the upgrade request, to determine an external access key associated with both the medical device to be upgraded and the desired upgrade based on the first product identifier;

providing, from the medical device supplier to the upgrade requester, the external access key associated with the medical device and the desired upgrade so that the upgrade requester can introduce the upgrade to the medical device responsive to the

external access key matching an internal access key associated with the medical device;

and

updating the database to indicate that the medical device has been upgraded with the desired upgrade.

50. The method of claim 49, wherein providing the external access key and the desired upgrade includes providing the external access key in a first medium and the desired upgrade in a second medium.

51. The method of claim 49, wherein updating the database includes providing a second product identifier associated with the medical device.